

DETAILED ACTION

This application is a 371 (national stage application) of PCT/GB05/00024.

Receipt of Amendments/Remarks filed on August 1, 2011, is acknowledged. In response to non-final Office Action dated March 31, 2011, applicant amended claim 77 and added no new claims. Claims 65-75, 77-92, 94-96, 98-103, 105, 107, & 109-113 are pending. Claims 65-75, 77-92, 94-96, 98-103, 105, 107, & 109-113 are under examination.

The following rejections and/or objections are reiterated. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1613

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 65-75, 77-92, 94-96, 98-103, 105, 107, & 109-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liers et al. (Medical and Veterinary Entomology, vol. 15, p299-303, cited by applicants on IDS) in view of the Petterino et al. (Veterinary and Human Toxicology, volume 43 issue 6, p353-360) and Jeannin et al. (US Patent 6,162,820).

Applicant claims

Applicant claims a rodenticidal composition comprising fipronil, a second generation rodenticide, and a feeding stimulant. Applicant also claims methods of using such a composition to kill fleas, ticks and their host rodents.

Determination of the scope and content of the prior art (MPEP 2141.01)

Liers et al. teach, as a whole, a composition containing fipronil, bromadiolone (a second generation rodenticide) and a feeding stimulant as well as methods of controlling fleas and the rats they inhabit.

Claims 65-73, 77-87, & 90-91: Liers et al. teach bait comprising fipronil, bromadiolone (a rodenticide) and crushed wheat (a cereal grain and feeding stimulant) (Materials and Methods section, especially page 300, first full paragraph). Liers et al. teach fipronil concentrations of 0.0005 and 0.005% and a rodenticide concentration of 0.005% with the remainder being feeding stimulant (Materials and Methods section, especially page 300, first 2 full paragraphs and table 2).

Claims 74 & 88: Liers et al. teach increasing the palatability of the bait by possibly adding rice (a cereal grain, hence an attractant) to the bait (p 303, last full paragraph).

Claims 75 & 89: Liers et al. teach using a solvent (acetone or propylene glycol) in the composition (p 300, third full paragraph and table 2).

Claims 92, 94-96, 98-103, 105, 107, & 109-113: Liers et al. teach a method of killing fleas and their host rats by providing a bait composition comprising 0.005% (50 ppm) fipronil and 0.005% (50 ppm) bromadiolone (a rodenticide) (Materials and Methods section, especially page 300 including tables 2 & 3, also Discussion section, Figure 2).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the teachings Liers et al. and the instant claims is that Liers et al. uses bromadiolone as the rodenticide, whereas the claims select the rodenticide from the group consisting of brodifacoum, difethialone, flocoumafen and

Art Unit: 1613

mixtures thereof. This deficiency in the teachings of Liers et al. is cured by the teachings of Petterino et al.

Petterino et al. teach bromadiolone, brodifacoum, difethialone, and flocoumafen are all useful as second-generation, anticoagulant rodenticides (page 353, 3rd paragraph). Petterino et al. also teach that bromadiolone has a higher LD₅₀ against rodents (less effective as a rodenticide) than brodifacoum, difethialone, and flocoumafen (page 355-357, tables 4, 5, 7, & 8).

The difference between the teachings Liers et al. and the instant claims is that Liers et al. use the bait composition in a method to kill fleas not ticks. This deficiency in the teachings of Liers et al. is cured by the teachings of Jeannin et al.

Jeannin et al. teaches, as a whole, methods for controlling ectoparasites with fipronil. Jeannin et al. specifically teaches that fipronil is useful for killing both ticks and fleas (column 4, lines 10-15).

**Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute brodifacoum, difethialone, or flocoumafen for bromadiolone in the bait and method of Liers et al. as well as using the bait and method against both fleas and ticks and produce the instant invention, because brodifacoum, difethialone, or flocoumafen are art-recognized as more effective rodenticides than bromadiolone and fipronil is art-recognized as both an insecticide and an acaricide. The skilled artisan would have been motivated to use brodifacoum,

Art Unit: 1613

difethialone, or flocoumafen instead of bromadiolone because the Petterino et al. teach that brodifacoum, difethialone, and flocoumafen are more potent rodenticides of the same type. The skilled artisan would have been motivated to use the bait composition taught by Liers et al. against ticks as well as fleas because Jeannin et al. teach that fipronil is effective against both fleas and ticks.

All the critical elements of the instant claims are disclosed. The amounts and proportions of each ingredient are result-effective parameters chosen to obtain the desired effects. It would be obvious to vary amounts of the ingredients to optimize the effect desired, depending upon the particular host species and application method of interest, reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects. Applicant has not provided any objective evidence of criticality, non-obvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability. The instant invention provides well-known old art-recognized compounds, with well-known art-recognized effects, applied by well-known art-recognized methods to achieve improved control as is well-known in the art.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in using brodifacoum, difethialone, or flocoumafen as a rodenticide in the

compositions and methods taught and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

5. Applicant's arguments filed August 1, 2011, have been fully considered but they are not persuasive.

Applicant argues that Leirs et al. is concerned with improving the palatability of the bromadiolone composition. While it is true that the Leirs et al. does discuss the improving the palatability, it concludes that the use of acetone as solvent is chiefly responsible and that the palatability of the composition was improved by using propylene glycol in place of acetone (page 302, paragraph left and right columns). Additionally, the recognition of a possible avenue of improvement by the prior art does not teach away from any and all other modifications. Specifically, the Supreme Court stated that the Federal Circuit had erred "by holding that courts and patent examiners should look only to the problem the patentee was trying to solve" (*KSR v. Teleflex*, 82 USPQ2d at 1397). In this sense, applicant's arguments are largely beside the point, as the claimed subject matter at hand is what is adjudged for obviousness, not what the prior art thought was a problem to be overcome. Note from MPEP 2141:

In *KSR*, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art," *Id.* at ___, 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent

Art Unit: 1613

that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at ___, 82 USPQ2d at 1395. The Supreme Court stated that there are “[t]hree cases decided after Graham [that] illustrate this doctrine.” *Id.* at ___, 82 USPQ2d at 1395. (1) “In *United States v. Adams*, . . . [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *Id.* at ___, 82 USPQ2d at 1395. (2) “In *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, . . . [t]he two [pre-existing elements] in combination did no more than they would in separate, sequential operation.” *Id.* at ___, 82 USPQ2d at 1395. (3) “[I]n *Sakraida v. AG Pro, Inc.*, the Court derived . . . the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at ___, 82 USPQ2d at 1395-96 (Internal quotations omitted.). The principles underlining these cases are instructive when the question is whether a patent application claiming the combination of elements of prior art would have been obvious.

Applicant further argues that “[t]here is no teaching or suggestion in Leirs that another rodenticide should be used in place of bromadiolone”. However, rationale or motivation for a modification does not have to be expressly stated in the prior art, and it certainly does not have to be contained in the primary reference, as the Petterino reference provides ample motivation to replace bromadiolone with a more active coumadin-based rodenticide. Further, applicant is incorrect; Leirs et al. teach that roof rats (*Rattus rattus*) are less susceptible to bromadiolone than Norway rats (*Rattus norvegicus*); hence, the ordinarily skilled artisan would be motivated from this teaching to use a different, more effective rodenticide for eliminating roof rats. Applicant is also misconstruing the examiner's use of the term “deficiency”. The examiner is using this term to refer to the difference between Leirs et al. and the claimed invention, which Petterino certainly cures.

The expected result remains the same; a combination rodenticide/fipronil composition is made in the absence of evidence to the contrary. No unexpected results

Art Unit: 1613

have been presented. Applicant's arguments are not persuasive, and the rejection under 35 U.S.C. §103(a) is maintained. The examiner cannot identify allowable subject matter and applicant is directed to MPEP 707.07(d), second and third paragraphs, for interpreting the examiner's stated ground of rejection.

Conclusion

Claims 65-75, 77-92, 94-96, 98-103, 105, 107, & 109-113 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. LEA whose telephone number is (571)270-5870. The examiner can normally be reached on Mon-Fri 7:30-3:30 ET.

Art Unit: 1613

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on (571)272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. R. L./
Examiner, Art Unit 1613

crl
/Ernst V Arnold/

Primary Examiner, Art Unit 1613